REMARKS

Reconsideration of this application is respectfully requested.

Claims 1-32 have been canceled, and claims 33-57 have been added to the application. The new claims are supported in the following representative passages of the application:

CLAIM	SUPPORT
33 and 46	Claims 1 and 2 Page 13, lines 9-11 Page 25, line 16 - page 26, line 26 [110]
34 and 47	Claims 1& 2 Page 13, lines 9-11 Page 25, line 16 - page 26, line 26 [131] to [141]
35 and 48	Claims 1& 2 Page 13, lines 9-11 Page 25, line 16 - page 26, line 26 Page 28, lines 1-6
36 and 49	Page 9, line 22 Page 9, lines 26-27 Page 9, lines 28-29
37	Page 9, lines 27-28
38 and 50	Page 24, lines 15-17
39 and 51	Page 24, lines 15-17
40 and 52	Page 22, lines 11-15
41 and 53	Page 22, lines 11-15
42 and 54	Page 22, lines 16-18
43 and 55	Page 22, lines 19-31

CLAIM	SUPPORT
44 and 56	Page 11, lines 13-15
45 and 57	Example 18 at page 56.

Claims 33-43 are directed to pharmaceutical compositions. Claim 44 is directed to the use of these compositions. Specifically, claim 44 is directed to a method of monitoring SIV infection in a monkey using the pharmaceutical compositions. Applicants courteously request that claim 44 be rejoined with claims 33-43 in the event the pharmaceutical composition claims are found to be allowable.

Applicants courteously acknowledge the Examiner's reconsideration of the restriction requirement. Applicants understand that SEQ ID NOS. 2, 4, and 5 have now been examined. All of the new claims read on these SEQ ID NOS.

It is unclear from the Office Action whether claim 12 has been examined. The Office Action indicated that claim 12 was examined, but in the following sentence it was indicated that claim 12 was withdrawn. Office Action at 2. Applicants respectfully request clarification of the restriction requirement as it applies to claim 12 so that they can preserve their right file a divisional application.

In addition, claim 27 is not mentioned in the Office Action. Applicants respectfully request clarification of the status of claim 27 in order to preserve their right to file a divisional application.

Claim Objections

Claim 26 was objected to as reciting "the method according to Claim 26." Office Action at 3. This objection has been obviated by the cancellation of this claim.

Claims 5, 6, 8, and 9 were objected to as being improper multiple dependent claims. *Id.* This objection has been obviated by the cancellation of these claims.

Claim Rejection - 35 U.S.C. §112, Second Paragraph

Claim 14 was rejected because of use of the trademark Gerbu®. Office Action at 3. This ground for rejection has been obviated by the cancellation of claim 14. The trademark Gerbu® does not appear in the new claims. Accordingly, this ground for rejection may be withdrawn.

Claim Rejections - 35 U.S.C. §112, First Paragraph - Written Description

Claims 1-9,12-16, 26, 28, and 32 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. According to the Office, there is insufficient written description support to demonstrate possession of a complete genus comprising peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOS: 1-9. Office Action at 6-7.

This ground for rejection has been obviated by the cancellation of claims 1-9, 12-16, 26, 28, and 32. The new claims do not recite "90% to 99.9999% sequence homology". Accordingly, this ground for rejection may be withdrawn.

Claim Rejections - 35 U.S.C. §112, First Paragraph - Enablement

Claims 1-9,12-16, 26, 28, and 32 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. According to the Office, the specification is enabling for SEQ ID NOS: 1 to 9. The Office contends, however, that the specification does not reasonably provide enablement for variants of these sequences that have 90% to 99.9999% sequence homology to SEQ ID NOS 1-9. Office Action at 7. This ground for rejection has been obviated by the cancellation of claims 1-9, 12-16, 26, 28, and 32. The new claims do not recite "90% to 99.9999% sequence homology". Accordingly, this ground for rejection may be withdrawn.

Claims 1-9,12-16, 26, 28, and 32 were also rejected under 35 U.S.C. §112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. According to the Office, the claims are drawn to pharmaceutical compositions and vaccine compositions comprising peptides of SEQ ID NOS 1-9 and peptide variants that have 90% to 99.9999% sequence homology to SEQ ID NOS 1-9. The Office concluded that the specification does not sufficiently support the claimed vaccines. Office Action at 10.

This ground for rejection has been obviated by the cancellation of claims 1-9, 12-16, 26, 28, and 32. None of the new claims recite peptide variants that have "90% to 99.9999% sequence homology". Moreover, a "vaccine" composition is not specifically recited in Applicants' claims. It will be understood, however, that the claimed "pharmaceutical composition" may be used as a vaccine, although Applicants are not

relying on this utility to meet the requirements of 35 U.S.C. §112. Accordingly, this ground for rejection may also be withdrawn.

Claim Rejections - 35 U.S.C. §102

Claims 1-4 and 12-14 were rejected under 35 U.S.C. §102(b) as being anticipated by Berman et al. (U.S. Patent 6,042,836; "Berman"). While these claims have been cancelled, they were drawn to a pharmaceutical composition comprising peptides of SEQ ID NOS: 1 to 9 and variants thereof, wherein the peptides immunologically react with antibodies raised against a CBD-1 or CBD-2 peptide. According to the Office, Berman discloses a vaccine composition that contains HIV proteins, such as gp41. Further, according to the Office, HIV gp41 is expected to have the motif of SEQ ID NO: 1. According to the Office, antibodies generated due to immunization of an animal with the whole gp41 protein will immunologically react with the caveolin-binding domain peptide of HIV-1. The Office further states that this disclosure by Berman anticipates the subject matter of Applicants' claims This ground for rejection is respectfully traversed and reconsideration is requested for the following reasons.

The presently claimed peptides had never been identified as having a B or T epitope prior to the filing of the present application. Therefore, Applicants' claims are not anticipated by Berman.

Moreover, the peptides of the invention are not glycosylated. This nonglycosylated state of the caveolin-binding motif comprising the claimed peptides makes it possible to elicit neutralizing antibodies, not produced in natural conditions. The Berman reference does not disclose this feature of Applicants' invention.

In other embodiments, Applicants' claims are directed to pharmaceutical compositions comprising at least one immunogenic peptide. The immunogenic peptide consists of nine amino acids (claim 46), thirteen amino acids (claim 47), or up to thirty-one amino acids (claims 48-56), and to the use of these pharmaceutical compositions for monitoring SIV infection in a monkey (claim 57). The Berman reference does not disclose these immunogenic peptides or their use as claimed by Applicants.

The Berman reference cannot anticipate Applicants' claims because it does not disclose each and every element of the claimed invention. *See* M.P.E.P. 2131. Accordingly, this ground for rejection may be withdrawn.

Claim Rejections - 35 U.S.C. §103

Claims 1, 4, 12-16, and 28 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dong et al. (Immunology Letters, 2001; "Dong"), in view of Rubinstein et al. (U.S. Patent 6,447,778; "Rubinstein"). According to the Office, Dong teaches SEQ ID NO: 1, a tryptophan rich motif with tryptophan residues at amino acid positions 623, 628, and 631 within the C domain of the gp41. Dong does not teach a pharmaceutically acceptable carrier, an adjuvant, or a composition, which is multimeric or polyvalent or encapsulated with a polymer. Rubinstein was cited as allegedly teaching a pharmaceutical composition comprising a peptide derived from gp41 protein of HIV, a pharmaceutically acceptable carrier, an adjuvant, multimeric and polyvalent presentation of peptides in the composition, and microencapsulation of peptides in the composition using polymers. The Office concluded that it would have been obvious to a person of ordinary skill in the art to provide a pharmaceutical composition comprising peptide motif of SEQ ID NO: 1, arranged in a polyvalent manner and encapsulated with

a polymer, in a pharmaceutically acceptable carrier, and an adjuvant. Office Action at 15. This ground for rejection is respectfully traversed, and reconsideration is requested for the following reasons.

The caveolin binding motif of gp41 is not exposed in fusion intermediates of gp41, unlike the N-domain and C-domain, because it is localized at the junction of the loop and the C-domain as shown in Fig. 1(a) of Dong et al. The discussion of Dong et al. at page 219, paragraph 7, deals with the potential protective/neutralizing activity of N- and C-domains because they are exposed on the fusion intermediates. So this conclusion could not be applied to the claimed peptides, which are not exposed, contrary to what is asserted by the Office. (Office Action page 14.)

As previously noted, in other embodiments, Applicants' claims are directed to pharmaceutical compositions comprising at least one immunogenic peptide. The immunogenic peptide consists of nine amino acids (claim 46), thirteen amino acids (claim 47), or up to thirty-one amino acids (claims 48-56), and to the use of these pharmaceutical compositions for monitoring SIV infection in a monkey (claim 57).

The Dong reference does not disclose immunogenic peptides consisting of nine amino acids. Similarly, the Dong reference does not disclose immunogenic peptides consisting of thirteen amino acids. Furthermore, the Dong reference does not disclose immunogenic peptides consisting of up to thirty-one amino acids. And finally, the Dong reference does not disclose the use of pharmaceutical compositions for monitoring SIV infection in a monkey.

Moreover, with respect to claim 46, Dong does not disclose a glutamine residue at position X_8 of the peptide as claimed.

With respect to claim 47, Dong does not disclose a glutamate residue at position R_3 or a lysine residue at position R_4 of the peptide as claimed.

Furthermore, with respect to claim 48, and the claims dependent therefrom, Dong does not disclose the aspartate residue at position X_{10} or the lysine residue at position X_{11} of the claimed peptides.

The Rubinstein reference does not remedy these deficiencies in the Dong reference. Rubinstein does not disclose pharmaceutical compositions containing the peptides recited in Applicants' claims.

To establish a *prima facie* case of obviousness, three basic criteria must be met. The prior art reference (or references when combined) must teach or suggest all the claim limitations. Also, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. In addition, there must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure.

Here, the threshold requirement for establishing a *prima facie* case of obviousness has not been met. The prior art references, even when combined, do not teach or suggest all of the limitations of claims 46, 47, 48, and the claims dependent therefrom. Accordingly, the rejection under 35 U.S.C. §103(a) must be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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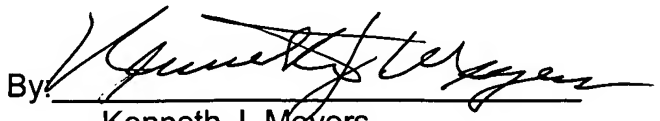
Dated: February 1, 2007

By: 

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